

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

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U.S. DISTRICT COURT  
DISTRICT OF MASS.

CIVIL ACTION No. 03-12221-MLW

**JURY TRIAL DEMANDED**

BAXTER HEALTHCARE CORPORATION,

Plaintiffs,

v.

THE TRUSTEES OF COLUMBIA  
UNIVERSITY IN THE CITY OF NEW  
YORK,

Defendant.

**ANSWER TO COMPLAINT**

Defendant The Trustees of Columbia University in the City of New York ("Columbia") responds as follows to the Complaint for Declaratory Judgment of Invalidity and Unenforceability of U.S. Patent No. 6,455,275, and that No Royalties are Owed (the "Complaint") of Plaintiff Baxter Healthcare Corporation ("Plaintiff").

1. In response to paragraph 1, Columbia admits and alleges that the United States Patent and Trademark Office ("PTO") issued United States Patent No. 4,399,216 (the "'216 Patent") on August 16, 1983, and that Columbia is the assignee of the '216 Patent. Columbia further admits and alleges that the contents of the '216 Patent speak for themselves. Columbia further admits and alleges that the '216 Patent expired on August 16, 2000. Columbia further admits and alleges that United States Patent No. 4,634,665 (the "'665 Patent") issued on January 6, 1987. Columbia further admits and alleges that United States Patent No. 5,179,017 (the "'017 Patent") issued on January 12, 1993. Columbia further admits and alleges that the '665 and '017 Patents claim priority to the application that issued as the '216 Patent and that these two patents expired on August 16, 2000. Columbia further admits and alleges that on September 24, 2002, the PTO issued United States Patent No. 6,455,275 (the "'275 Patent"), and that Columbia is the

assignee of the '275 Patent. Columbia further admits and alleges that the contents of the '275 Patent speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 1, and further denies that Plaintiffs are entitled to any relief whatsoever requested in the Complaint.

2. In response to paragraph 2, Columbia admits and alleges that the '216 Patent issued on August 16, 1983. Columbia further admits and alleges that the '665 Patent issued on January 6, 1987. Columbia further admits and alleges that the '017 Patent issued on January 12, 1993. Columbia further admits and alleges that the contents of the '216, '665, and '017 Patents speak for themselves. Columbia further admits and alleges that on February 25, 1980, United States Application No. 06/124,513 (the "'513 Application") was filed. Columbia further admits and alleges that the prosecution histories of the '216, '665, and '017 Patents speak for themselves. Columbia further admits and alleges that the '216, '665, and '017 Patents expired on August 16, 2000. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 2.

3. In response to paragraph 3, Columbia admits and alleges that it has licensed the '216 Patent, as well as related patents and patent applications, to more than thirty companies. Columbia further admits and alleges that it has received more than \$100 million in payments through its licensing through the fourth quarter of 2000. Columbia further admits and alleges that it proposed legislation that, if enacted into law, would have allowed Columbia to apply for an extension of the '216 Patent. Columbia further admits and alleges that Congress did not enact into law the legislation that Columbia proposed. Columbia further admits and alleges that the '216, '665, and '017 Patents expired on August 16, 2000. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 3.

4. In response to paragraph 4, Columbia admits and alleges that in 2000 it was prosecuting patent applications. Columbia further admits and alleges that the contents of these applications speak for themselves. Columbia further admits and alleges that in 1995 it filed the applications that were pending in 2000. Columbia further admits and alleges that the '275 Patent issued on September 24, 2002, and that the '275 Patent expires on September 24, 2019. Columbia further admits and alleges that the contents of the '275 Patent and its prosecution history speak for themselves. Columbia further admits and alleges that the contents of the '216, '665, and '017 Patents, and their prosecution histories, speak for themselves. Columbia further admits and alleges that it informed licensees of the '275 Patent about its existence. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 4, and further denies that Plaintiffs are entitled to any relief whatsoever requested in the Complaint.

5. In response to paragraph 5, Columbia admits and alleges that Plaintiff is a Delaware corporation with offices in Illinois. Columbia further admits and alleges that Plaintiff markets RECOMBINATE® and ADVATE®. Columbia further admits and alleges that in 1990 Genetics Institute, Inc. ("GI") entered into a license agreement with Columbia (the "GI License Agreement"). Columbia further admits and alleges that the contents of the GI License Agreement speak for themselves. Columbia further admits and alleges that in 1997 it entered into a license agreement with Plaintiff (the "Baxter License Agreement"). Columbia further admits and alleges that the contents of the Baxter License Agreement speak for themselves. Except as so expressly admitted and alleged, Columbia is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 5 and denies them on that basis.

6. In response to paragraph 6, Columbia admits and alleges that Columbia is a non-profit corporation organized and existing under the laws of the State of New York and that it is located in the City of New York, State of New York. Columbia further admits and alleges that it is the assignee of the '216, '665, '017, and '275 Patents. Columbia further admits and alleges that it entered into the Baxter License Agreement, and that the contents of this License Agreement speak for themselves. Columbia further admits and alleges that U.S. Patent No. 5,149,636 (the "'636 Patent") issued on September 22, 1992, and that Columbia is the assignee of the '636 Patent. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 6.

7. In response to paragraph 7, Columbia admits and alleges that the rules regarding jurisdiction set forth in 28 U.S.C. §§ 1331, 1332(a)(1), 1338(a), 2201(a), and 2202 speak for themselves. Columbia further admits and alleges that the amount of royalties that Plaintiff owes or will owe to Columbia during the term of the '275 Patent exceeds \$75,000 and that this action is between citizens of different states. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 7.

8. In response to paragraph 8, Columbia admits and alleges that the rules regarding venue set forth in 28 U.S.C. § 1391(b) speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 8.

9. In response to paragraph 9, Columbia admits and alleges that Richard Axel, Michael H. Wigler, and Saul J. Silverstein carried out research. Columbia further admits and alleges that the results of some of this research are contained in the '513 Application. Columbia further admits and alleges that the contents of the '513 Application and its prosecution history

speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 9.

10. In response to paragraph 10, Columbia admits and alleges that Richard Axel, Michael H. Wigler, and Saul J. Silverstein carried out research. Columbia further admits and alleges that the results of some of this research are contained in the '513 Application. Columbia further admits and alleges that the contents of the '513 Application and its prosecution history speak for themselves. Columbia further admits and alleges that on February 25, 1980, the '513 Application was filed, identifying Richard Axel, Michael H. Wigler, and Saul J. Silverstein as inventors. Columbia further admits and alleges that the '513 Application issued as the '216 Patent on August 16, 1983. Columbia further admits and alleges that the contents of the '216 patent and its prosecution history speak for themselves. Columbia further admits and alleges that the '216 Patent expired on August 16, 2000, seventeen years after issuance. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 10.

11. In response to paragraph 11, Columbia admits and alleges that the inventions described in the '216 Patent were made in the course of work under grants from the National Institutes of Health, Department of Health and Human Services. Columbia further admits and alleges that Columbia received a letter dated February 24, 1981, from Charles Miller, Assistant Secretary for Health, Department of Health and Human Services, and that the contents of this letter speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 11.

12. In response to paragraph 12, Columbia admits and alleges that the '216 patent issued on August 16, 1983. Columbia further admits and alleges that on August 11, 1983, United States Application No. 06/522,408 (the "'408 Application") was filed. Columbia further

admits and alleges that the contents of the '408 Application and its prosecution history speak for themselves. Columbia further admits and alleges that the patent laws applicable to continuation applications speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 12.

13. In response to paragraph 13, Columbia admits and alleges that the '408 Application was filed on August 11, 1983. Columbia further admits and alleges that the '408 Application issued as the '665 Patent on January 6, 1987. Columbia further admits and alleges that the contents of the '665 Patent and its prosecution history speak for themselves. Columbia further admits and alleges that the patent laws applicable to a terminal disclaimer speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 13.

14. In response to paragraph 14, Columbia admits and alleges that on October 3, 1983, United States Application No. 06/915,273 (the "'273 Application") was filed. Columbia further admits and alleges that the contents of the '273 Application and its prosecution history speak for themselves. Columbia further admits and alleges that on May 2, 1989, United States Application No. 07/346,089 (the "'089 Application") was filed. Columbia further admits and alleges that the contents of the '089 Application and its prosecution history speak for themselves. Columbia further admits and alleges that on June 18, 1991, United States Application No. 07/716,915 (the "'915 Application") was filed. Columbia further admits and alleges that the contents of the '915 Application and its prosecution history speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 14.

15. In response to paragraph 15, Columbia admits and alleges that the '915 Application issued as the '017 Patent. Columbia further admits and alleges that the contents of

the '017 Patent and its prosecution history speak for themselves. Columbia further admits and alleges that the contents of the '216 and '665 Patents, and the '513 Application, speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 15.

16. In response to paragraph 16, Columbia admits and alleges that it has prosecuted applications through the present that claim priority to the '513 Application. Columbia further admits and alleges that the '275 Patent issued on September 24, 2002, and that the contents and prosecution history of that patent speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 16.

17. In response to paragraph 17, Columbia admits and alleges that on June 7, 1995, it filed United States Application Nos. 08/484,136 (the "'136 Application") and 08/477,159 (the "'159 Application"). Columbia further admits and alleges that the contents of these two applications and their prosecution histories speak for themselves. Columbia further admits and alleges that the patent laws governing patent applications filed both before and on or after June 8, 1995, speak for themselves. Columbia further admits and alleges that on September 24, 2002, the '136 Application issued as the '275 Patent. Columbia further admits and alleges that the '275 Patent expires on September 24, 2019. Columbia further admits and alleges that the '159 Application is still pending. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 17.

18. In response to paragraph 18, Columbia admits and alleges that Richard Axel and James M. Roberts carried out research. Columbia further admits and alleges that the results of some of this research are contained in United States Application No. 06/358,206 (the "'206 Application"), filed March 15, 1982. Columbia further admits and alleges that the contents of



the '206 Application and its prosecution history speak for themselves. Columbia further admits and alleges that on December 17, 1984, United States Application No. 06/683,251 (the "'251 Application") was filed. Columbia further admits and alleges that the contents of the '251 Application and its prosecution history speak for themselves. Columbia further admits and alleges that on October 1, 1987, United States Application No. 07/103,807 (the "'807 Application") was filed. Columbia further admits and alleges that the contents of the '807 Application and its prosecution history speak for themselves. Columbia further admits and alleges that on September 26, 1988, United States Application No. 07/249,454 was filed and that this application issued as the '636 Patent on September 22, 1992. Columbia further admits and alleges that the contents of the '636 Patent and its prosecution history speak for themselves. Columbia further admits and alleges that the prosecution history of the '275 Patent speaks for itself. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 18.

19. In response to paragraph 19, Columbia admits and alleges that in 1990 it entered into the GI License Agreement, and that the contents of the GI License Agreement speak for themselves. Columbia further admits and alleges that in 1997 it entered into the Baxter License Agreement, and that the contents of the Baxter License Agreement speak for themselves. Columbia further admits and alleges that Plaintiff markets RECOMBINATE®. Except as so expressly admitted and alleged, Columbia is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 19 and denies them on that basis.

20. In response to paragraph 20, Columbia admits and alleges that in 1997 it entered into the Baxter License Agreement, and that the contents of the Baxter License Agreement speak



for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 20.

21. In response to paragraph 21, Columbia admits and alleges that the contents of the Baxter License Agreement speak for themselves. Columbia further admits and alleges that it has received more than \$100 million in payments through its licensing through the fourth quarter of 2000. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 21.

22. In response to paragraph 22, Columbia admits and alleges that the '216, '665, and '017 Patents expired on August 16, 2000. Columbia further admits and alleges that it proposed legislation that, if enacted into law, would have allowed Columbia to apply for an extension of the '216 Patent. Columbia further admits and alleges that Congress did not enact into law the legislation that Columbia proposed. Columbia further admits and alleges that the statements made to Congress speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 22.

23. In response to paragraph 23, Columbia admits and alleges that the statements made to Congress speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 23.

24. In response to paragraph 24, Columbia admits and alleges that its statements to Congress speak for themselves. Columbia further admits and alleges that its statements to the PTO speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 24.

25. In response to paragraph 25, Columbia admits and alleges that it proposed legislation that, if enacted into law, would have allowed Columbia to apply for an extension of

the '216 Patent. Columbia further admits and alleges that Congress did not enact into law the legislation that Columbia proposed. Columbia further admits and alleges that the '216, '665, and '017 Patents expired on August 16, 2000. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 25.

26. In response to paragraph 26, Columbia admits and alleges that on June 7, 1995, it filed the '136 and '159 Applications. Columbia further admits and alleges that the contents of these applications, the '216, '665, and '017 Patents, the '513 Application, and their prosecution histories, speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 26.

27. In response to paragraph 27, Columbia admits and alleges that the patent laws governing the '136 and '159 Applications speak for themselves. Columbia further admits and alleges that the patent laws governing continuation applications filed after June 7, 1995, speak for themselves. Columbia further admits and alleges that the prosecution histories of the '136 and '159 Applications speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 27.

28. In response to paragraph 28, Columbia admits and alleges that the '136 Application was filed on June 7, 1995, and that it issued as the '275 Patent on September 24, 2002. Columbia further admits and alleges that the '159 Application was filed on June 7, 1995, and is still pending. Columbia further admits and alleges that the '513 Application was filed on February 25, 1980. Columbia further admits and alleges that the '216, '665, and '017 Patents expired on August 16, 2000. Columbia further admits and alleges that the contents of the '275 Patent and its prosecution history speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 28.

29. In response to paragraph 29, Columbia admits and alleges that the contents and the prosecution history of the '275 Patent speak for themselves. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 29.

30. In response to paragraph 30, Columbia admits and alleges that the contents of the '275, '665, and '017 Patents, and their prosecution histories, speak for themselves. Columbia further admits and alleges that the '275 Patent expires on September 24, 2019. Columbia further admits and alleges that the '216 Patent issued on August 16, 1983, and expired on August 16, 2000. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 30.

31. In response to paragraph 31, Columbia admits and alleges that it informed licensees of the '275 Patent that it had issued. Columbia further admits and alleges that the contents of the GI License Agreement and the Baxter License Agreement speak for themselves. Columbia is without knowledge or information sufficient to form a belief as to the truth of Plaintiff's allegations regarding its contractual obligations to GI and denies them on that basis. Except as so expressly admitted and alleged, Columbia denies each and every allegation of paragraph 31.

#### **Count I**

32. In response to paragraph 32, Columbia incorporates herein by this reference paragraphs 1 through 31 of the Answer as if set forth in full.

33. In response to paragraph 33, Columbia admits and alleges that the '275 Patent falls within the definition of Licensed Patent Rights under the GI License Agreement and that GI is obligated to pay royalties to Columbia pursuant to the terms of that agreement. Columbia is without knowledge or information sufficient to form a belief as to the truth of Plaintiff's